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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,335	09/28/2000	Joseph M. Cummins	5523-67250	7680

23643 7590 06/18/2002

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EXAMINER

WINKLER, ULRIKE

ART UNIT PAPER NUMBER

1648

DATE MAILED: 06/18/2002

34

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/672,335

Applicant(s)

CUMMINS ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Note the original claim 40 has been renumbered claim 39 as per rule 126.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-9, drawn to a method of reducing an acute inflammation by administering INF-gamma, classified in class 424, subclass 9.2.
2. Claims 10-14 and 39, drawn to a method of treatment or prevention of an INF sensitive disease using INF-gamma, classified in class 435, subclass 7.24.
3. Claims 15-23 and 38, drawn to a method of treatment or prevention of a bacterial or fungal infection using INF-gamma, classified in class 435, subclass 32.
4. Claims 24-28, drawn to a pharmaceutical formulation of INF-gamma, classified in class 424, subclass 85.4.
5. Claims 29-37, drawn to a method of activating B cells using INF-gamma, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because of the following reasons:

Group 4 is a composition and is distinct from groups 1-3 and 5 which are drawn to methods. Groups 1-3 and 5 are drawn to methods and each is distinct from the other because they utilize different targets for treatment, therefore the outcomes are not be expected to be the same. Groups 1 are drawn to a method for reducing an inflammation by treating a patient with INF-gamma. Group 2 is drawn to the prevention or treatment of a patient who has a INF-

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gamma sensitive disease. Group 3 is drawn to the treatment or prevention of bacterial or fungal infections with INF-gamma. Group 5 is drawn to the activation of B cells with INF gamma. Though there may be overlap between these methods in question for groups 1-3 and 5, each utilizes different treatment protocols and has different starting points therefore the outcome is expected to be different for each method. The methods differ in their physical and immunological properties and the diseases contemplated differ in their etiology and are distinct and unobvious in view of each other and are therefore patentably distinct. The examination of different method parameters would require different searches in the scientific literature and would involve the consideration of separate issues in determining patentability.

Inventions 4 and 1-3 and 5 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case other anti-inflammatory products as well as antibiotics and antifungals can be used to treat inflammatory diseases, bacterial infection or fungal infection.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294.

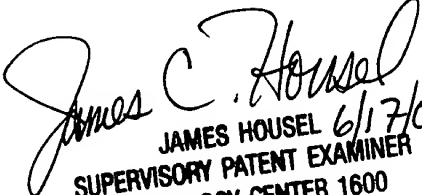
The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 or for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Ulrike Winkler, Ph.D.


JAMES HOUSEL 6/17/02
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600